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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,500	09/29/2006	Jong Soo Woo	Q97453	9881

23373 7590 09/14/2007

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EXAMINER	
HUANG, GIGI GEORGIANA	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/599,500	WOO ET AL.	
	Examiner	Art Unit	
	GiGi Huang	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/29/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-5 are present for examination at this time.

Information Disclosure Statement

2. The information disclosure statement filed September 29, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The non-patent reference by Lalor BC et al. has not been submitted. The information referred to therein has not been considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanghvi et al. (U.S. Pat. Publication No. 2007/0109891) in view of Shell et al. (U.S. Pat. No. 6340475).

Sanghvi et al. teaches a composition for sustained release of metformin or a pharmaceutically acceptable salt comprising metformin, at least one hydrophilic

compound, at least one cross-linking agent, and a at least one diluent (additive). An especially preferred hydrophilic compound is xanthan gum. Sanghvi teaches that the hydrophilic compound however can be any known in the art and mixtures of two or more are envisioned. Especially preferred crosslinking agents for the embodiments are guar gum, locust bean gum and mixtures thereof. The ratios of metformin to hydrophilic compound/cross-linking agent is generally in the range of about 1:0.1 to about 1:2. The specific examples 2-15 address the drug: gum ratios of 1:0.3, 1:0.5, 1:0.7, 1:0.9, 1:0.98 to list a few. The ratios exemplified fulfill the limitations of the claims. (Page 2, paragraph 22 ,25, Page 3, paragraph 26, Pages 6-10, Examples 2-15).

Sanghvi et al. does not expressly teach the combination of polyethylene oxide and xanthan gum.

Shell et al. teaches compositions comprising metformin hydrochloride. Shell teaches that the water-swellable polymers can be used individually or in combination. Shell also teaches that certain combinations will provide greater controlled release of the drug than when used individually. Shell taught that the specific combination of polyethylene oxide and xanthan gum would provide a greater controlled release of the drug than when each polymer component was used individually (Col. 9, lines 40-50).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate the combination of metformin hydrochloride, xanthan gum, polyethylene oxide, and a cross-linking agent as suggested by Shell et al., and produce the instant invention. Shell has taught that the specific combination of polyethylene oxide and xanthan gum would be desirable as that combination would

provide a greater controlled release of the drug than when each polymer component was used individually. When a combination of the polyethylene oxide and xanthan gum is used in the ratios exemplified, the ratios addressed above would continue to fulfill the limitations of the claims.

One of ordinary skill in the art would have been motivated to do this because a formulation that has a stable sustained release of a hydrophilic drug like metformin and its salts, prevents dose-dumping (sudden release of the drug), which is very desirable for sustained bioavailability of metformin, especially in a diabetic where stable resulting blood levels is critical.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.

5. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shell et al. (U.S. Pat. No. 6340475).

Shell et al. teaches a drug controlled release formulation comprising drugs in polymeric matrices that are water-swellable. Specifics are exemplified with metformin hydrochloride. A water-swellable polymer particularly preferred is poly(ethylene oxide). Preferred polyethylene oxides have an average molecular weight of about 100,000 (1×10^5) to about 10,000,000 (1×10^7). Xanthan gum is also preferred can be also used in the formulation.

Shell teaches that the water-swellable polymers can be used individually or in combination. Shell also teaches that certain combinations will provide greater controlled release of the drug than when used individually. Shell taught that the specific combination of polyethylene oxide and xanthan gum would provide a greater controlled release of the drug than when each polymer component was used individually.

The ratio of drug to polymer range in general from 0.01:99.99 to about 80:20, and the specific examples have ratios of 250:138.67 (equals 1.8), 79.6:20 (3.98), 79.6/15 (5.31), 79.6:18.05 (4.41), 64:35 (1.83) fulfilling the limitations of the claim (1:0.01 to 1:1 which equals 100-1). Other pharmaceutical additives such as magnesium stearate are also taught in the formulation (Abstract, Col. 5, lines 57-63, Col. 6, lines 38-42, Col. 8, lines 29-55, col. 9, lines 40-50, Col. 12, Example 1, Col. 13-14, Example 4-5, Claims 1, 3-4, 9).

Shell et al. does not expressly teach a specific example with metformin hydrochloride with xanthan gum and polyethylene oxide combined and the drug to polymer ratio with the combination.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate the combination of metformin hydrochloride, xanthan gum, and polyethylene oxide, as suggested by Shell et al., and produce the instant invention. While there is not a specific example present, Shell has taught that the specific combination of polyethylene oxide and xanthan gum would be desirable as that combination would provide a greater controlled release of the drug than when each polymer component was used individually. When a combination of the polyethylene oxide and xanthan gum is used in the ratios exemplified, the ratios addressed above would continue to fulfill the limitations of the claims.

One of ordinary skill in the art would have been motivated to do this because a formulation that has a stable sustained release of a hydrophilic drug like metformin and its salts, prevents dose-dumping (sudden release of the drug), which is very desirable for sustained bioavailability of metformin, especially in a diabetic where stable resulting blood levels is critical.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

All the critical elements are taught by the cited reference and thus the claims are rejected.

Conclusion

6. Claims 1-5 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GiGi Huang whose telephone number is (571) 272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

Zohreh Fay (Primary Examiner)